AUG 4 2000

Byron Medical Confidential - TRADE SECRET

510(k) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92

The assigned 510(k) number is: K001803

Submitted by: Regina S. Harris
Director of Regulatory Affairs
Byron Medical, Inc.
602 West Rillito Street
Tucson, AZ 85705

Telephone #: (520) 573-0857
Facsimile #: (520) 746-1757

Date Prepared: 19 May 2000

Establishment Registration Number: Byron Medical is located at 602 West Rillito Street, Tucson, AZ 85705. We are registered with the Food and Drug Administration as Establishment Number 2025576.

Classification Name:

Suction Lipoplasty Devices
21 CFR § 878.5040 (1998)

Manual Surgical Instrument for General Use
21 CFR § 878.4800 (1998)

Surgical Instrument Motors and Accessories/ Attachments
21 CFR § 878.4820 (1998)

Common/Usual Name: Surgical Aspiration and Lipoplasty Instrument

Proprietary Name: **Accelerator Reciprocating Cannula**

Indication for Use: The **Accelerator Reciprocating Cannula** indications for use are for removal of soft tissue or fluid from the body during general surgical procedures to include suction lipoplasty for the purpose of aesthetic body contouring.

Byron Medical Confidential

RE: **K001803** (Comment Response Letter to FAX: 05 July 2000)
510(k) Submission: Accelerator Reciprocating Cannula

More Detailed Substantial Equivalence Comparison with respect to rate and travel distance.

Cannula Action	Summary	Byron Medical Accelerator Reciprocating Cannula	MicroAire PAD system	Byron Medical - **Traditional** Cannula powered by average physician
Rate of Movement	Is **much lower** than the MicroAire device, and slightly higher that traditional manual movement. Thus, safely between the two existing technologies.	**0-800 cpm** – adjustable for variable surgeon technique and tissue variance patient to patient.	**0 and 4,000 cpm** non adjustable.	**0 - 250 cpm** based on physician stroke length. Not an easily maintainable rate.
Distance Travels	**Very similar** to the MicroAire device, and considerably less than traditional	**0, ¼" and ½"**	**0, 1/10" and ¼"**	**0 – 12"+**
Cannula attached	**Very similar** to both existing technologies	**2-6mm**	**3.9-5mm**	**2- 6mm**
Force	**Less than both existing modalities**, and presents surgeons with consistent controlled movement. Also, the **Byron Accelerator Reciprocating Cannula is the only device that provides a safety mechanism,** that when greater than 41 lbs of force is applied, the reciprocation stops to identify to surgeons that they are exerting greater than 40 lbs of force in dense tissue.	**41 lbs of force**	**60+ lbs of force** **The physician can overcome this force and apply 60 + physician force to be a very large delivery force.**	**50+ lbs of force**
Summary	With respect to function, the Byron Medical Reciprocating Cannula is as safe as the Existing Modalities with An additional safety feature of a relief mechanism of not applying a joint force of physician use greater than 41lbs of force.			

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 4 2000

Ms. Regina S. Harris
Director of Regulatory Affairs
Byron Medical, Inc.
602 W. Rillito Street
Tucson, Arizona 85705

Re: K001803
Trade Name: Accelerator Reciprocating Cannula
Regulatory Class: II
Product Code: MUU
Dated: July 5, 2000
Received: July 13, 2000

Dear Ms. Harris:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Vochmer

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001803

Device Name: **Accelerator Reciprocating Cannula**

Indications for Use:

The Accelerator Reciprocating Cannula indications for use are the removal of tissue or fluid from the body during general surgical procedures including suction lipoplasty for the purpose of aesthetic body contouring.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dianne R. Vachon

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001803

Prescription Use ✓
(Per 21 CFR 801.109

Over-The Counter Use _____

(Optional Format 1-2-96)